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Decision Guide on Selection of Personal Protective Equipment for Ebola Virus Disease - Isolation Gowns or Suits

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This document has been updated as of October 14, 2014, based on the best available evidence at that time. Version changes are summarized at the end of this document. Please refer to the Public Health Ontario website at www.publichealthontario.ca/ebola for the most recent version.

Selection of the range of personal protective equipment (PPE) supplied by an organization for the assessment and care of a patient with suspected or confirmed Ebola Virus Disease (EVD) needs to be based on a site-specific risk assessment that includes a review of the care level and tasks anticipated, work and environmental conditions, and controls in place. This assessment will determine the correct PPE required for protection of the staff members who provide direct care or support services throughout the continuum of care, from out-patient assessment to critical care to recovery or mortuary care. Organizations will need to customize their inventory to ensure that the PPE selected offers effective protection for the users. Several different designs or options may be required to be able to fit different staff.

Barrier protection is used to prevent non-intact skin or mucous membrane exposure of the eyes, nose and mouth with blood, other body fluids, secretions or excretions. Hand hygiene at key moments and sequencing of PPE removal (doffing) is critically important to prevent accidental self-contamination. Staff training on the care, use, benefits and limitations of all of the PPE selected by the organization for care of a patient with suspected or confirmed EVD is required as part of a comprehensive planning and preparation process.
The type of gown or protective clothing selected should be based on the nature of the interaction with the client or patient, including:

- anticipated degree of contact with infectious material
- risk posed by EVD
- potential for blood and body fluid penetration of the gown
- duration of potential exposure

The use of protective clothing for EVD may evolve, and the type and level of protection may need to increase as the condition of the patient changes.

Inherent in the selection of PPE for EVD in each setting is the need to assess the following factors:

- Comfort and usability for staff – "wearability"
    - Available in a wide range of sizes to fit different body types (PPE that is too small may tear)
    - Design allows for proper range of motion involved in the completion of expected tasks and does not impede movement (potential for injury, trip hazard etc.)
    - Ease of donning and doffing without self-contamination in the process
    - Assessment of comfort when wearing for extended periods of time
- Supply chain availability and ability to source and replenish stock and sizes easily if needed

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Isolation Gown Standards

There is currently no established guidance that specifies performance criteria for PPE that is specific to EVD. The performance criteria included in the Canadian Standards Association Z314.10.1-10 "Selection and use of gowns, drapes and wrappers in health care facilities" should be used in selecting isolation gowns. See Table 1. These CSA standards also mirror the Association for the Advancement of Medical Instrumentation (AAMI) standards.

It is important to note that in the CSA standard the "Critical Zones" for isolation gowns encompasses the entire gown including the front and back. For surgical gowns the critical zones are the front panel and sleeves only. Using a surgical gown in an isolation setting would not necessarily provide full protection.

Table 1: Summary of Barrier Classification and tests (Adapted from CSA Z314.10.1 and AAMI PB70:2012)[1, 2]

	Material	Resistance to fluid penetration	Testing measure	Isolation:
CSA Level 1 AAMI Level 1 (fluid resistant)	Spunbond nonwoven fabric	Minimal water resistance	AATCC 42 (test for resistance to spray)	This would be the minimum standard for isolation gowns where minimal amounts of spray or droplets are anticipated.
CSA Level 2 AAMI Level 2 (fluid resistant)	Single layer microfibers or is a topically treated textile material	Resistant to water spray and some resistance to water absorption on contact.	AATCC 127 (test for resistance to water on contact; hydrostatic pressure) AATCC 42 (test for resistance to water spray)	Commonly used as an isolation gown; suitable for situations involving low amounts of fluid or low risk of sprays.
CSA Level 3 AAMI Level 3 (fluid resistant)	Laminated or coated material e.g. polypropylene coated polypropylene gowns	Resistant at a higher standard to water spray and resistance to water absorption on contact	Meets a higher test standard (compared to Level 2) for fluid resistance based on ATCC 127 (test for resistance to water on contact; hydrostatic pressure) AATCC 42 (test for resistance to water spray)	Used where more moderate amounts of fluid exposure or sprays may be anticipated in the course of providing patient care or handling of body fluids
CSA Level 4 AAMI Level 4 (fluid impermeable)	Laminated or coated materials (e.g. impervious polyethylene)	Resistant to penetration of viruses based on penetration of a surrogate microbe for Hepatitis (B and C) and the Human Immunodeficiency Viruses.	All critical components meets requirements of the bacteriophage penetration test ASTM F1671	Used where large amounts of fluids or sprays may be anticipated or encountered.

Manufacturers may cite other references to testing criteria used for gowns or protective clothing. For instance a manufacturer may cite an "ISO" standard for fluid resistance (for example ISO16603 or 16604)[3, 4]. Others may simply reference the test method used such as ASTM 1670 or ASTM 1671, without actually referencing the AAMI or CSA standard. For instance, with full body suits, there is no reference in CSA or AAMI because both of these standards are more specific to gowns (drapes, etc.).

Protective clothing that meets ASTM for fluid resistance has been tested for resistance to a synthetic blood challenge (see below). All materials that pass ASTM test 1671 have also passed ASTM 1670. A product that has passed ASTM 1671 (which includes any gown that is level 4 based on AAMI/CSA) is therefore one of the most desirable protective clothing for circumstances where there is high probability for blood and body fluid exposure where infectious agents are present.

It is important to note that these tests utilize arbitrary values that may not always reflect the actual reality of end-use.

ISOLATION GOWN SELECTION CRITERIA:

Gowns used as PPE should be cuffed and long-sleeved, and offer full coverage of the body front, from neck to mid-thigh or below and fully overlap in the back with adequate closures to keep the gown secured.

SCREENING /TRIAGE SETTINGS:

A gown that meets the CSA/AAMI Standard for "Isolation Gown" as **level 2** (fluid resistant) gown is sufficient for those encounters for triage, initial screening, brief interactions and moving of a patient to an isolation room for further investigation or assessment.

PATIENT CARE:

In selection of gowns for use in providing direct care for patients with increasing symptoms of EVD, the gown should meet the CSA/AAMI Standard for "Isolation Gown" as a **Level 3** (fluid resistant) or **Level 4** (fluid impermeable). Choice of fluid resistant or fluid impermeable will be made based on the risk and amount of fluid exposure anticipated during the patient or patient environment encounter.

PROTECTIVE CLOTHING/ONE-PIECE SUITS SELECTION CRITERIA:

There are a wide range of full body suits available that provide coverage of the body and head, depending on their design. Integrated foot coverings, gloves and face protection or respiratory protection may be available. These suits have been designed for wide variety of applications from protection against dry particulates to chemical and liquid splash-resistance.

Suits are not part of the AAMI or CSA standards for gowns. However, in the selection of suits for use in caring for patients with EVD, the fabric should meet at least the CSA/AAMI Standard Level 3 or 4 (fluid resistant or fluid impermeable), or reference ASTM 1670 or 1671 or other standard that is based on ASTM testing. The seams and closures may have less barrier performance than the material. Suits that are constructed with taped or sealed seams would be required along with other techniques that reduce the risk and volume of

contact with body fluids (addition of fluid impervious aprons, absorbent materials to reduce volume of fluids, other barriers etc.).

> **Manufacturers should be consulted to review the performance criteria of the selected suits and suitability of that suit for use in a medical setting.**

End-users need to also determine if the suits provide enough range of sizes to be able to fit all staff. Suits that are too small may tear as the user bends or squats. Suits that are too large may catch or snag on equipment or objects. The suit also needs to accommodate the use of any additional PPE required.

A final area of consideration is the ease of donning or doffing of the suit and the amount of space and extra assistance required to do this safely.

Use of gowns or protective suits with other PPE

When a protective gown or suit is selected it is important that other PPE is compatible and fits to make a proper ensemble. For example gloves may leave a gap between the sleeve and the glove when the arm is outstretched. Longer gloves will be needed if there is a gap.

Where hoods are part of the personal protective equipment, it is important that masks, face-shield and respirators as needed, will not dislodge or become occluded as the hood is applied and the health care worker moves during the provision of care.

Occupational Health and Safety requirements shall be met. Health care facilities are required to comply with applicable provisions of the Occupational Health and Safety Act (OHSA), R.S.O. 1990, c.O.1 and its Regulations.

PPE FAILURE:

Staff members require training on the use and limitations of all PPE and measures to take should the PPE be breached. This will include careful removal of the damaged PPE and removal of any leaked blood and body fluids on intact skin with soap and water. Clear protocols must be in place for any blood or body fluid exposure including puncture, splash or spray to mucous membranes.

References

1. Canadian Standards Association. CSA Z314.10.1-10 - Selection and use of gowns, drapes, and wrappers in health care facilities. Mississauga, ON: CSA; 2010.

2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI PB70:2012 - Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Arlington, VA: AAMI; 2012.

3. International Organization for Standardization. ISO 16603:2004 - Clothing for protection against contact with blood and body fluids - Determination of the resistance of protective clothing materials to penetration by blood and body fluids - Test method using synthetic blood. Geneva: ISO; 2004.

4. International Organization for Standardization. ISO 16604:2004 - Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage. Geneva: ISO; 2004.